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Application Number: 09/676/670
Applicant: Scherr, George H.
Art Unit: 1617
Title: Alginate Foam Compositions
This Application is a CIP of
09/301,228 04/29/1999 ABN
Examiner: Dr. Shahnam Sharareh

To: Dr. Shahnam Sharareh United States Patent&Trademark Office
From: Dr. George H. Scherr

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Dear Dr. Sharareh:

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OFFICIAL

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Dear Dr. Sharareh:

I have reviewed your detailed action and comments pertinent to my application and the comments contained therein are appreciated and well taken. I now withdraw claims 1 to 19 from further consideration and attached herein are new claims from 55 to 104. There are two process claims now before us. These process claims have a common generic or linking claim.

I note the comments made by the examiner with regard to the citations of ostensibly prior art. With the examiner's permission I should like to reserve my comments of the prior art cited by the examiner until the examiner has had the opportunity to review the attached new claims, except to set forth the following:

The patent of Strong (US Patent No. 3,948,881) describes a process for the preparation of alkylene glycol alginates. There is absolutely no resemblance either in the methodology of preparation nor in the purported use of the synthesis described by Strong and the preparations described in my pendent application. A mere examination of the abstract of Strong in his patent is sufficient to distinguish the total lack of relationship between the two documents in that Strong starts with free alginic acid, which is then esterified in situ in the solid seaweed (emphasis added) from which the alginic acid is to be extracted and then the alkylene glycol alginate has to be recovered by chemical extraction methods described in Strong's patent. We treat no chemicals with an alkylene oxide, we perform no work at all with alginic acid, we do not extract any chemicals from any seaweeds, and none of the products or components that are described by Strong can in anyway lend themselves to result in a preparation which even vaguely resembles the product we describe in our application that could be used in the preparation of wound dressings or surgical products.

I also wish to make a brief commentary concerning the patent by Cole, et al. (U.S. Patent No. 5,089,606). Cole et al. utilized a double barrel syringe. Into each of the two barrels of the syringe are inserted two separate compounds, which then react when released through a common exit applicator. Therefore this device is used directly in situ for the treatment of various pathological states. Cole, et al. describe their methodology with the utilization of a water-insoluble di- or trivalent metal salt. This water-insoluble di- or trivalent metal salt component is a major component in practically all of the claims of Cole et al. In our application we cannot possibly start with a water-insoluble di- or trivalent metal salt, since our purpose is to insolubilize the water soluble alginate component. We therefore have to add a di- or trivalent cation metal ion salt that would be capable of complexing with the water soluble alginate to then form a water-insoluble alginate hydrogel. These two methods are completely diverse in their chemical synthesis, their starting components, and in the methodology by which they can be used for treating a pathological state. In the case of my pendent application we dry the composite mixture so prepared and place it onto a cloth which will act as a suitable secondary dressing for the alginate product so prepared, whereas in the Cole, et al. patent, the mixture so made in this double-barrel device has to be used 'as is' and then a secondary dressing has to be placed over it, to hold in place.

Please note that in claim 15 of the patent by Cole, et al., the methodology uses di- or trivalent salts, all of which are aqueous insoluble, an attribute which would make totally unfeasible the final product had we started with any one of those insoluble di- or trivalent metal salts.

The insoluble metal salts utilized by Cole, et al. must be made soluble by reacting with water-soluble acids (See column 6, lines 29-35). Examples of suitable acids include alginic acid amongst others. Alginic acid is an aqueous-insoluble acid and could not possibly act as a water soluble acid neither in the patent of Cole, et al. and certainly not in our application, in order to convert the insoluble metal ion salts to soluble metal ion salts. If one were to examine column 2, lines 5-13 of the patent by Strong, it quite clearly sets forth that alginic acid is recovered by treating with sulphuric acid resulting in an aqueous insoluble precipitate (of alginic acid) and the insoluble nature of alginic acid is totally inconsistent with the cited solubility of alginic acid by Cole, et al.

I submit that the Cole, et al. as well as the Strong patent are both sufficiently divorced from the methodology in my pendent application that they could not serve as prior art.

Respectfully submitted,

George H. Scherr, Ph.D.

GHS/jj

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CLAIMS 55-104

55. A process for making a water-insoluble alginate sponge or foam product to be utilized in the preparation of wound dressings or surgical products comprising the steps of:

(I) making an aqueous solution of a water-soluble alginate composition;

(II) while allowing the total composition of (I) to be mixed, adding a di-or trivalent cation metal ion salt capable of complexing the water-soluble alginate to form a water-insoluble alginate hydrogel;

(III) adding to the mixture of (II), a plasticizer, a surface active agent, sodium tetraborate, ammonium hydroxide, and a suitable medicinal agent;

(IV) while continuing to mix the entire composition (III), producing a foam in the composition (III) by introducing a biocompatible gas into said composition;

(V) pouring said composite mixture of (IV) onto a fibrous cloth contained in or on a tray, which fibrous cloth will become affixed to the alginate composition after the aqueous component of said composite mixture has evaporated.

56. The process of claim 55 where said gas producing the foam is selected from a group consisting of nitrogen, carbon dioxide, argon, neon, or mixtures thereof.

57. The process of claim 55 in which the fibrous cloth is selected from cloths prepared from cotton, polyester, wool, nylon, rayon, or mixtures thereof.

58. The process of claim 55 wherein said water-soluble alginate is selected from a group consisting of ammonium, magnesium, potassium, sodium salts of alginate, or mixtures thereof.

59. The process of claim 55 wherein said di- or trivalent cation is selected from a metal ion derived from salts selected from the group consisting of alkaline earth metal salts, alkali metal salts, transition metal salts, and mixtures thereof.

60. The process of claim 55 wherein said metal cation is selected from the group consisting of calcium, barium, copper, magnesium, iron, zinc, aluminum, manganese, silver, strontium, and mixtures thereof.

61. The process of claim 55 wherein said medicament is selected from the group consisting of collagen, maltodextrin, antibiotics, antibact rial agents, anti-inflammatory agents, ascorbic acid, amino acids, and mixtures thereof.

62. The process of claim 55 wherein said plasticizer is selected from a group consisting of glycerin, propylene glycol, ethylene glycol, and polyethylene glycol or mixtures thereof.

A1 CONT.

63. The process of claim 55 wherein said surface active agent is selected from a group consisting of polyoxyethylene sorbitan monolaurate, polyoxyethylene sorbitan monopalmitate, polyoxyethylene sorbitan monooleate, polyoxyethylene sorbitan trioleate, polyoxyethylene-polyoxypropylene block polymer, or a mixture thereof.

64. The process of claim 55 wherein the di- or trivalent cation metal salt complexing the water soluble alginate is calcium sulphate.

65. The process of claim 55 where in the di- or trivalent cation metal salt complexing the water soluble alginate is calcium chloride.

66. A water-insoluble alginate sponge or foam wound dressing prepared by the method of claim 55.

67. A water-insoluble alginate sponge or foam wound dressing prepared by the method of claim 56.

68. A water-insoluble alginate sponge or foam wound dressing prepared by the method of claim 57.

69. A water-insoluble alginate sponge or foam wound dressing prepared by the method of claim 58.

70. A water-insoluble alginate sponge or foam wound dressing prepared by the method of claim 59.

71. A water-insoluble alginate sponge or foam wound dressing prepared by the method of claim 60.

72. A wat r-insoluble alginat sponge or foam wound dressing prepared by the method of claim 61.

A1 CONT.

73. A water-insoluble alginate sponge or foam wound dressing prepared by the method of claim 62.

74. A water-insoluble alginate sponge or foam wound dressing prepared by the method of claim 63.

75. A water-insoluble alginate sponge or foam wound dressing prepared by the method of claim 64.

76. A water-insoluble alginate sponge or foam wound dressing prepared by the method of claim 65.

77. A process for making a water-insoluble alginate sponge or foam product to be utilized in the preparation of wound dressings or surgical products comprising the steps of:

(I) making an aqueous solution of a water-soluble alginate composition;

(II) while allowing the total composition of (I) to be mixed, adding a di-or trivalent cation metal ion salt capable of complexing the water-soluble alginate to form a water-insoluble alginate hydrogel;

(III) adding to the mixture of (II), a plasticizer, a surface active agent, sodium tetraborate, ammonium hydroxide, and a suitable medicinal agent;

(IV) while continuing to mix the entire composition (III), adding an effervescent compound capable of effervescence upon reaction with a water-soluble acid;

(V) adding to the composition (IV) a water-soluble acid;

(VI) pouring said composite mixture of (V) onto a fibrous cloth contained in or on a tray, which fibrous cloth will become affixed to the alginate composition after the aqueous component of said composite mixture has evaporated.

78. The process of claim 77 wh rein the effervescent compound is selected from a group consisting of the alkali metal carbonates.

A1 cont.

79. The process of claim 78 wherein said effervescent compound is sodium carbonate.

80. The process of claim 77 wherein said effervescent compound is sodium bicarbonate.

81. The process of 77 wherein said water soluble acid is selected from the group consisting of acetic, lactic, malic, gluconic, hydrochloric, and ascorbic acids.

82. The process of claim 77 in which the fibrous cloth is selected from cloths prepared from cotton, polyester, wool, nylon, rayon, or mixtures thereof.

83. The process of claim 77 wherein said water-soluble alginate is selected from a group consisting of ammonium, magnesium, potassium, sodium salts of alginate, or mixtures thereof.

84. The process of claim 77 wherein said di- or trivalent cation is selected from a metal ion derived from salts selected from the group consisting of alkaline earth metal salts, alkali metal salts, transition metal salts, and mixtures thereof.

85. The process of claim 77 wherein said metal cation is selected from the group consisting of calcium, barium, copper, magnesium, iron, zinc, aluminum, manganese, silver, strontium, and mixtures thereof.

86. The process of claim 77 wherein said medicament is selected from the group consisting of collagen, maltodextrin, antibiotics, antibacterial agents, anti-inflammatory agents, ascorbic acid, amino acids, and mixtures thereof.

87. The process of claim 77 wherein said plasticizer is selected from a group consisting of glycerin, propylene glycol, ethylene glycol, and polyethylene glycol or mixtures thereof.

88. The process of claim 77 wherein said surface active agent is selected from a group consisting of polyoxyethylene sorbitan monolaurate, polyoxyethylene sorbitan monopalmitat ,

polyoxyethyl ne sorbitan mono leate, polyoxyethyl ne sorbitan trioleate, polyoxyethylene-polyoxypropylene block polymer, or a mixture th reof.

89. The process of claim 77 wherein the di- or trivalent cation metal salt complexing the water soluble alginate is calcium sulphate.

90. The process of claim 77 where in the di- or trivalent cation metal salt complexing the water-soluble alginate is calcium chloride.

91. A water-insoluble alginate sponge or foam wound dressing prepared by the method of claim 77.

92. A water-insoluble alginate sponge or foam wound dressing prepared by the method of claim 78.

93. A water-insoluble alginate sponge or foam wound dressing prepared by the method of claim 79.

94. A water-insoluble alginate sponge or foam wound dressing prepared by the method of claim 80.

95. A water-insoluble alginate sponge or foam wound dressing prepared by the method of claim 81.

96. A water-insoluble alginate sponge or foam wound dressing prepared by the method of claim 82.

97. A water-insoluble alginate sponge or foam wound dressing prepared by the method of claim 83.

98. A water-insoluble alginate sponge or foam wound dressing prepared by the method of claim 84.

99. A water-insoluble alginate sponge or foam wound dressing prepared by the method of claim 85.

100. A water-insoluble alginate sponge or foam wound dressing prepared by the method of claim 86.

101. A water-insoluble alginate spong or foam wound dressing prepared by th method f claim 87.

Cont.

102. A water-insoluble alginate sponge or foam wound dressing prepared by the method of claim 88.

103. A water-insoluble alginate sponge or foam wound dressing prepared by the method of claim 89.

104. A water-insoluble alginate sponge or foam wound dressing prepared by the method of claim 90